



March 30, 2025

Avatar Medical  
Adeline Francois  
VP QARA and Clinical Affairs  
11 rue de Lourmel  
Paris, 75015  
France

Re: K243292

Trade/Device Name: brAIn™ Shoulder Positioning  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: LLZ, QIH  
Dated: February 14, 2025  
Received: February 14, 2025

Dear Adeline Francois:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jessica Lamb, PhD  
Assistant Director  
Imaging Software Team  
DHT8B: Division of Radiological Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K243292

Device Name  
brAIn™ Shoulder Positioning

Indications for Use (Describe)

brAIn™ Shoulder Positioning is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510(k) Summary

Device Name: [brAln™ Shoulder Positioning](#)

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### Device Name: [brAln™ Shoulder Positioning](#)

#### 2.1 Submission correspondent [↗](#)

Table 2A – Submission correspondent

<b>510(k) Sponsor</b>	Avatar Medical
<b>Address</b>	11 rue de Lourmel 75015 Paris France
<b>Correspondence Person</b>	FRANCOIS Adeline VP QARA and Clinical Affairs
<b>Contact Information</b>	Email: <a href="mailto:adeline@avatarmedical.ai">adeline@avatarmedical.ai</a>
<b>Date of Submission</b>	October 2024

#### 2.2 Subject Device [↗](#)

Table 2B – Subject Device

<b>Trade Name</b>	brAln™ Shoulder Positioning
<b>Common Name</b>	Planning Software for Total Shoulder Arthroplasty
<b>Classification Name</b>	System, Image Processing, Radiological
<b>Regulation Number</b>	21 CFR 892.2050
<b>Regulation Name</b>	Medical Image Management and Processing System

<b>Product Code:</b>	QIH, automated radiological image processing software
<b>Subsequent Product Code:</b>	LLZ, system, image processing, radiological
<b>Regulatory Class</b>	II
<b>Classification Panel</b>	Radiology

## 2.3 Predicate Device [↗](#)

Table 2C – Predicate Device

<b>Trade name</b>	FX SPS
<b>Common Name</b>	Planning software for Total Shoulder Arthroplasty
<b>Premarket Notification</b>	K213922
<b>Classification Name</b>	System, Image Processing, Radiological
<b>Regulation Number</b>	21 CFR 892.2050
<b>Regulation Name</b>	Medical Image Management and Processing System
<b>Product Code</b>	LLZ
<b>Regulatory Class</b>	II
<b>Classification Panel</b>	Radiology

## 2.4 Device Description [↗](#)

The brAln™ Shoulder Positioning software is a cloud-based application intended for shoulder surgeons. It is used to plan primary anatomic and reverse total shoulder replacement surgeries using FX Shoulder Solutions implants. The software is accessible via a web-based interface, where the user is prompted to upload their patient's shoulder CT-scan (DICOM series) accompanied with their information in a dedicated interface. The software automatically segments (using machine learning) and performs measurements on the scapula and humerus anatomy contained in the DICOM series. These segmentations are used for planning, which includes an interactive 3D viewer that allows for soft tissue visualization. Implants for the glenoid and humerus are positioned using this same 3D interface through a dedicated manipulation panel. The changes in shoulder anatomy resultant from the implants are relayed in a post-position interface that displays information related to distalization and lateralization. The software outputs a planning multimodal summary that includes textual information (patient information, pre- and post-op measurements) and visual information (screen captures of the shoulder pre- and post-implantation).

## 2.5 Indications for Use Statement [↗](#)

brAln™ Shoulder Positioning is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

## 2.6 Substantial Equivalence Discussion [↗](#)

The following table compares brAln™ Shoulder Positioning to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed

information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

**Table 2D: Comparison of Characteristics**

<b>Feature/ Function</b>	<b>Predicate Device:</b> FX SPS (K213922)	<b>Subject Device:</b> brAln™ Shoulder Positioning
<b>Intended Users</b>	Healthcare Professionals	Healthcare Professionals
<b>Intended Environment</b>	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
<b>Device Class</b>	Class II	Class II
<b>Type of software</b>	Web-based software	Web-based software
<b>Use time</b>	Pre-operatively	Pre-operatively
<b>Imaging used</b>	CT-scan images	CT-scan images
<b>Type of implants planned</b>	Anatomical and reverse shoulder implants	Anatomical and reverse shoulder implants
<b>Manual/Automatic segmentation</b>	Manual segmentation performed.	Automatic segmentation performed.
<b>User profiles</b>	User profiles define the authorized actions for the user.	User profiles define the authorized actions for the user.
<b>Case management</b>	List of cases	List of cases
<b>Tools</b>	Milling tool	Milling tool (called reaming)
<b>Patient Information Display</b>	<ul style="list-style-type: none"> <li>• Patient last name</li> <li>• Patient first name</li> <li>• Patient sex</li> <li>• Patient birthdate</li> <li>• Shoulder side</li> <li>• Surgery date</li> </ul>	<ul style="list-style-type: none"> <li>• Patient last name</li> <li>• Patient first name</li> <li>• Patient sex</li> <li>• Patient birthdate</li> <li>• Patient age</li> <li>• Patient height</li> <li>• Patient weight</li> <li>• Shoulder side</li> <li>• Surgery date</li> </ul>
<b>Bone representation</b>	3D and 2D representation of the humerus and the scapula	3D and 2D representation of the humerus and the scapula.
<b>2D DICOM Viewer</b>	2D DICOM view  Axial views are displayed in 2D DICOM Viewer interfaces.	The 2D DICOM Viewer Interface displays 2D DICOM images  Axial and coronal views are displayed in two separate 2D DICOM Viewer interfaces.

<b>3D Viewer</b>	3D reconstruction in an interactive viewing interface	3D reconstruction in an interactive viewing interface with soft tissues (Pre-Position Interface only)
<b>Planning step</b>	<ul style="list-style-type: none"> <li>• Case details,</li> <li>• Segmentation,</li> <li>• Glenoid</li> </ul>	<ul style="list-style-type: none"> <li>• Create plan,</li> <li>• Validate Segmentations,</li> <li>• Pre-position with the validation of Shoulder Landmarks,</li> <li>• Implant,</li> <li>• Glenoid/humerus,</li> <li>• Post position,</li> <li>• Surgical planning Report</li> </ul>
<b>Landmarks / Measurements</b>	Manual measurements performed: Shoulder Measurements, scapula neck length, posterior subluxation, glenoid reaming depth.	Pre-positioning or Semi-automatic measurements performed: Shoulder Measurements, baseplate Seating, posterior subluxation, glenoid reaming depth.
<b>Implant Initial Placement</b>	Manual initial placement performed.	Pre-positioning or Semi-automatic initial placement performed.
<b>Planning report</b>	Planning report comprising preoperative and planned parameters.	Planning report comprising patient information, implant and measurement pre and Post position, with 8 images to illustrate the chosen implant configuration.
<b>Recommendations</b>	Does not include any predictions and recommendations.	Does not include any predictions and recommendations.

The performance of brAln™ Shoulder Positioning was validated by nonclinical tests. All verification testing met the acceptance criteria (passed), demonstrating that the software fulfills its requirement specifications.

## 2.7 Predicate Device Comparison [↗](#)

The subject device and the primary device have similar indications for use in that they are both intended to use CT-scan imaging and the intended type of implants and duration of use are also similar.

The **brAln™ Shoulder Positioning** has minor differences from the predicate device.

Internal verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the predicate device. The testing results support that the Software validation of the product was met for the acceptance of the device. **brAln™ Shoulder Positioning** passed all testing and supports the claims of substantial equivalence to the predicate device.

Overall, these differences do not raise new questions of safety or effectiveness and therefore the subject device is substantially equivalent to the predicate device.

## 2.8 Performance Data [↗](#)

Software Verification and Validation Tests:

Safety and performance of the brAln™ Shoulder Positioning has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. The model was evaluated taking into account applicable requirements of the FD&C Act and 2081 implementing regulations.

Additionally, the software validation activities were performed in accordance with *ANSI AAMI IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes*, in addition to the FDA Guidance documents, “*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*” and “*Content of Premarket Submission for Management of Cybersecurity in Medical Devices*.”

#### Segmentation Performance Testing:

The brAln™ system's automatic segmentation was validated against manual segmentation, meeting a mean Dice Similarity Coefficient (DSC) on the testing set greater than or equal to 0.95. All tests confirmed that the segmentation performance meets the acceptance criteria, ensuring compliance.

The automatic segmentation provided by brAln™ Shoulder Positioning was validated against manual segmentation performed. The validation criterion was a Dice Similarity Coefficient (DSC) coefficient of 0.95 or higher, demonstrating that the segmentation produced by the model after post-processing closely matches the ground truth.

The dataset is comprised of 508 pairs of 3D images (DICOM series) together with their segmentation labels. The 3D images have on average 467 (axial) slices of resolution 512x512 pixels.

The dataset is divided into two partitions:

- **Training Set** (65.9%, 335 samples)
  - **Shoulder Side:** 43.3% left (145), 56.7% right (190)
  - **Gender:** 57.9% female (84), 41.4% male (60), 0.7% unspecified (1) for left; 57.4% female (109), 42.1% male (80), 0.5% unspecified (1) for right
  - **Geographical Origin:** 46.9% Europe (68), 56.4% USA (77) for left; 52.6% Europe (100), 47.4% USA (90) for right
- **Testing Set** (34.1%, 173 samples)
  - **Shoulder Side:** 45.7% left (79), 54.4% right (94)
  - **Gender:** 55.7% female (44), 44.3% male (35) for left; 63.8% female (60), 36.2% male (34) for right
  - **Geographical Origin:** 58.2% Europe (46), 41.8% USA (33) for left; 56.4% Europe (53), 43.6% USA (41) for right

The data corresponds to patients that underwent a total shoulder arthroplasty with an FX Shoulder implant without any further specific selection, representing a diversity in shoulder side, patient gender, imaging equipment, institutions, study year and geographical provenance. The protocol used for image acquisition is standard for patient undergoing a total shoulder arthroplasty.

The labels were created manually by medical professionals.

To prevent any form of data leakage, we took the following precautions: first, the training and testing datasets were split at the patient level to ensure that no patient data was included in both sets. Second, to ensure both a representative split of the dataset, we performed a stratified split based on patient gender, shoulder side and geographical region of origin. With this approach, we ensure that both sets accurately reflect the intended patient population. Besides, we decided to boost the representation of study collected in 2024 in the testing dataset compared to the training dataset, enabling thus a better generalization on future images and increased independence between datasets.

#### Shoulder Side Detection performance testing:

Validation compared the correct shoulder side (right or left) in DICOM images to a manual assessment performed by a Clinical Solutions Specialist. All performance tests for Shoudler Side Detection validation were successfully completed with no deviations, confirming compliance with the required performance standards.

#### Measurement Accuracy performance testing:

Validation compared the accuracy of the brAln™ Shoulder Positioning software measurement when editing the position of landmarks within the software to the reported accuracy of the predicate. All performance tests for Measurement Accuracy Validation were successfully completed with no deviations, confirming compliance with the required performance standards.

#### Landmark Performance Testing:

Validation compared pre-positioning with final positions adjusted by experts, achieving accuracy similar to manual positioning with a 3 mm mean distance as the acceptance criterion. All performance tests for landmark validation were successfully completed with no deviations, confirming compliance with the required performance standards.

## **2.9 Statement of Substantial Equivalence**

The brAln™ Shoulder Positioning is as safe and effective as the predicate device. The brAln™ Shoulder Positioning has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device.

The minor technological differences between the brAln™ Shoulder Positioning and its predicate device raise no new issues of safety or effectiveness. The performance data demonstrates that the brAln™ Shoulder Positioning is as safe and effective as the predicate device.

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

brAln™ Shoulder Positioning, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.